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10/594,758	09/29/2006	Yoshihiro Nomura	296946US0PCT	5292
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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314				
EXAMINER TSAY, MARSHA M				
ART UNIT		PAPER NUMBER		
1656				
NOTIFICATION DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/594,758

Applicant(s)

NOMURA ET AL.

Examiner

Marsha M. Tsay

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

This Office action is in response to Applicants' remarks received December 29, 2008.

Applicants' arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn.

Claim 6 is canceled. Claims 1-5, 7-19 are currently under examination.

Priority: The request for priority to JAPAN 2004-107286, filed March 31, 2004, is acknowledged.

The declaration under 37 CFR 1.132 filed December 29, 2008 is sufficient to overcome the rejection of claims 1-3 based upon Shiojima et al. (US 6066316) as a single 103(a) reference. However, upon further review of the instant claim set, the Shiojima et al. reference is still believed to be relevant art under 103(a) in view of Mullner et al. (WO 0236801 abstract).

Objections and Rejections

Claims 14-16 are objected to because of the following informalities: claims 14-16 are dependent on claim 10, which already recites a neutralizing step, therefore the term "further" is believed to be unnecessary. Appropriate correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites an average molecular weight of 8,000 to 13,000. It is unclear what units the MW is, i.e. kDa, Da, etc. Further clarification is requested.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8, 9, 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Arai et al. (US 5763583). Arai et al. teach a solubilized keratin product that is treated with an oxidizing agent, i.e. hydrogen peroxide (col. 4 lines 1-4, col. 7-8 examples 1-4; claims 8, 9, 19). The solubilized keratin product is suitable for use in a cosmetic composition (col. 6 lines 20-24; claim 10). Claim 8 is included in this rejection because of the indefiniteness regarding the MW as noted in the 112, 2nd, rejection above. While instant claims 8, 9, and 19 are product-by-process claims, the product of said claims is believed to be the same as the keratin product of Arai et al. since both the instant keratin and the keratin of Arai et al. are treated with hydrogen peroxide (and would therefore be odorless and colorless) and are suitable for use in cosmetic compositions.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shiojima et al. (US 6066316; previously cited) in view of Mullner et al. (WO 0236801 abstract). Shiojima et al. disclose pretreated and/or washed keratin (i.e., hair, wool, etc.) can be hydrolyzed by alkali solutions having a concentration between 1 to 20% in general (col. 22 lines 1-10, 39-40). Further, the hydrolysis reaction is conducted at room temperature to 100°C and for 30 minutes to 24 hours (col. 22 41-43). In Synthesizing Example 3(II) and (IV), Shiojima et al. disclose keratin raw material was immersed in aqueous solution, hydrolyzed in alkali solution, said keratin-alkali solution was neutralized, and filtered to obtain a keratin hydrolyzate (col. 28). Shiojima et al. also disclose that salt can be removed by a membrane step (col. 28 lines 40-41). Shiojima et al. do not explicitly teach a hydrous state of 20 to 80% or an alkali concentration of 0.1 to 0.5 mol/L.

Mullner et al. teach keratin protein hydrolysates obtained from keratinous waste (i.e. wool, feathers, hooves, etc.) are suitable for use in cosmetic compositions (p. 3). Mullner et al. teach that the substrate is a natural proteinaceous product preferably with a water content of 5-99 weight %, especially a substrate containing keratin (p. 4). The final keratin protein product contains substantially no toxic constituents (p. 4).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Shiojima et al. by substituting the keratin material (having a

water content in the range of 5-99 wt %) of Mullner et al. for the raw keratin used in Shiojima et al. (claims 1-4, 7-13, 17-19). The motivation to do so is given by Mullner et al., which teach that using a keratinous substrate having a water content in the range of 5-99 weight % in a protein hydrolysis process can eliminate toxic constituents in the final keratin protein product.

Regarding the limitation of an alkali concentration of 0.1 to 0.5 mol/L, generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical.

"[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Therefore, "the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."; *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969). For more recent cases applying this principle, see *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). MPEP 2144.05.

Shiojima et al. also disclose that said keratin raw material can be hydrolyzed by acidic solutions having a concentration between 3 to 85% in general (col. 22 lines 15-20). Further, said keratin raw material can be treated with hydrogen peroxide (col. 23 lines 24-34, col. 26 lines 40-41).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Shiojima et al. by using the various hydrolysis processes alone or in combination (i.e. acidic treatment and/or hydrogen peroxide treatment) for the treatment of said keratin material of Mullner et al. (having a water content in the range of 5-99 wt %) in order to obtain a solubilized keratin protein product (claims 5, 14-16). Since Shiojima et al. disclose various treatment steps that can be applied to the keratin raw material, it would be reasonable for one of ordinary skill to combine and/or execute the various treatment steps in order to obtain an optimum solubilized keratin protein product. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In this instance, the normal desire of scientists to determine which steps and/or components should be included in a process for producing solubilized keratin without toxic constituents and that are suitable for use in a cosmetic compositions provides the motivation to determine the optimum working conditions.

Applicant's arguments have been fully considered and are persuasive to overcome the previous 103(a) rejections over Shiojima et al. However, the Shiojima et al. is still believed to be relevant art in view of the newly cited Mullner et al. reference.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maryam Monshipouri/

Primary Examiner, Art Unit 1656

March 20, 2009